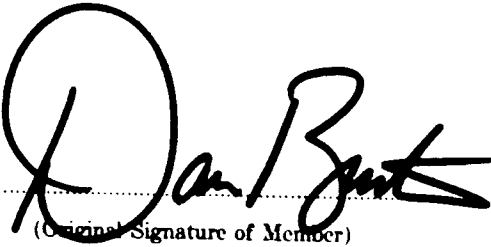


H.L.C.  
  
(Original Signature of Member)

106TH CONGRESS  
2D SESSION

**H. R.** \_\_\_\_\_

\_\_\_\_\_  
**IN THE HOUSE OF REPRESENTATIVES**

Mr. BURTON (for himself [**see attached list of cosponsors**]) introduced  
the following bill; which was referred to the Committee on \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act to  
restrict the authority of the Food and Drug Administra-  
tion to issue clinical holds regarding investigational drugs  
or to deny patients expanded access to such drugs.

1       *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Thomas Navarro FDA  
3 Patient Rights Act”.

4 **SEC. 2. INVESTIGATIONAL NEW DRUGS; RESTRICTIONS ON**  
5 **AGENCY AUTHORITY REGARDING CLINICAL**  
6 **HOLDS ON TRIALS AND EXPANDED ACCESS**  
7 **FOR PATIENTS.**

8 (a) CLINICAL HOLDS.—Section 505(i)(3) of the Fed-  
9 eral Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)(3))  
10 is amended by adding at the end the following subpara-  
11 graph:

12 “(D) The Secretary may not under clause  
13 (i) or (ii) of subparagraph (B) place a clinical  
14 hold on an investigation of a drug on the basis  
15 that the Secretary has determined that—

16 “(i) there is another drug (including  
17 another investigational drug) that is or  
18 may be a safe and effective therapy for the  
19 disease or condition involved; or

20 “(ii) there is a comparable or satisfac-  
21 tory alternative therapy available for a pa-  
22 tient who is receiving or will receive the  
23 drug as a clinical subject in the investiga-  
24 tion, except that such restriction on the  
25 authority of the Secretary applies only if  
26 the patient declares in writing that the pa-

1           tient is aware of the comparable or satis-  
2           factory alternative therapy, is aware of the  
3           risk involved in receiving the drug in the  
4           investigation, and chooses to receive the  
5           drug notwithstanding such risk and not-  
6           withstanding the comparable or satisfac-  
7           tory alternative therapy.”.

8       (b) EXPANDED ACCESS.—

9           (1) INDIVIDUAL PATIENT ACCESS.—Section  
10          561(b)(1) of the Federal Food, Drug, and Cosmetic  
11          Act (21 U.S.C. 360bbb(b)(1)) is amended by insert-  
12          ing before the semicolon the following: “, except that  
13          such conditions for the receipt by the person of the  
14          investigational drug do not apply if the person de-  
15          clares in writing that the person is aware that there  
16          is a comparable or satisfactory alternative therapy,  
17          is aware of the risk involved in receiving the inves-  
18          tigational drug, and chooses to receive the drug not-  
19          withstanding such risk and notwithstanding the  
20          comparable or satisfactory alternative therapy”.

21          (2) TREATMENT APPLICATION.—Section  
22          561(c)(2) of the Federal Food, Drug, and Cosmetic  
23          Act (21 U.S.C. 360bbb(c)(2)) is amended by insert-  
24          ing before the semicolon the following: “, except that  
25          such condition for the receipt by a patient of an in-

1       vestigational drug does not apply if the patient de-  
2       clares in writing that the patient is aware that there  
3       is a comparable or satisfactory alternative therapy,  
4       is aware of the risk involved in receiving the inves-  
5       tigational drug, and chooses to receive the drug not-  
6       withstanding such risk and notwithstanding the  
7       comparable or satisfactory alternative therapy”.

**Original Co-Sponsors for the Thomas Navarro FDA Patient's Rights Act as  
Introduced by Dan Burton of Indiana on February 16, 2000**

Bob Barr of Georgia  
Joe Barton of Texas  
John Doolittle of California  
Ben Gilman of New York  
Stephen Horn of California  
Walter Jones of North Carolina  
Ray Lahood of Illinois  
John McHugh of New York  
David McIntosh of Indiana  
Carrie Meek of Florida  
Ron Paul of Texas  
Jim Ryun, Kansas  
Joe Scarborough of Florida  
Bob Stump of Arizona